Institutional Profile

Site Name: Meharry Medical College

Last modified date: 01/29/2020

ABOUT THE INSTITUTIONAL PROFILE
The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance. This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website [here](#). This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Meharry Medical College</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00003675</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-01-04</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000529</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Please see uploaded roster</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
</tbody>
</table>

Section 2: SITE-SPECIFIC LOCAL CONTEXT
This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization. Additional, study-specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements). However, any information
provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).

To what state laws is your institution subject?
- TN

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of majority in your state?</td>
<td>18</td>
</tr>
<tr>
<td>What circumstances affect age of consent in your state?</td>
<td>N/A</td>
</tr>
<tr>
<td>For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment</td>
<td></td>
</tr>
<tr>
<td>Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule?</td>
<td>No</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>Yes, I will insert language in text box</td>
</tr>
<tr>
<td>Please insert the language required to be used around mandatory reporting to health authorities.</td>
<td>We do not have specific language but Meharry will inform the Investigator to detail the method for obtaining informed consent for HIV testing in research as part of the initial study submission to the IRB or provide a description of the process for de-identifying blood samples taken from participants. The Investigator may also request a waiver of informed consent, when appropriate. The Meharry Medical College (MMC) Institutional Review Board (IRB) assures that HIV testing associated with human research participants is congruent with Federal, State and local regulations. This procedure outlines the processes to assure that human immunodeficiency virus (HIV) testing associated with human research participants under the jurisdiction of the MMC IRB is congruent with Federal, State and local regulations.</td>
</tr>
<tr>
<td>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</td>
<td>No</td>
</tr>
<tr>
<td>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does the site have a posted policy for the following? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</td>
<td>Consent Process for those with Impaired Decision-Making Capacity, Use of short forms for non-English speaking individuals, Translation of consent forms for non-English speaking individuals</td>
</tr>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Please enter your specific consent form language regarding payment for research-related injury.

The following language preferably should be included in the consent document, unless specifically waived by the IRB: "If you are injured because you are in this study, you can get reasonable, immediate, and necessary medical care for your injury at MMC without charge to you. There are no plans for MMC to pay for the costs of care beyond your injury, or to give you money for such injury. For commercially sponsored studies, compensation or payment of immediate necessary care for injury related to participation in research activities shall be provided according to the contractual agreement between the sponsor and MMC. The following language is incorporated into the consent document, unless specifically waived by the IRB: "If you are injured by the investigational {drug, device, item or procedure} because you are in this study, you can get reasonable, immediate, and necessary medical care for your injury at MMC without charge to you. There are no plans for MMC to pay for the costs of care beyond your injury, or to give you money for such injury. You will still be responsible for the cost of treatments and tests you receive during the study that are not investigational. These are the treatments and tests you would need whether you are in this study or not. The cost of treating your illness or underlying condition and the cost of treating any injuries that are caused by these routine tests or treatments while you are in the study will be billed to you or your insurance company. If for any reason these costs are not covered by insurance, you will have to pay the costs." 3. For research sponsored by the Department of Defense, the following compensation language is required: "If you are hurt or get sick because of this study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the Principal Investigator for this study, (insert name and phone number here). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the Principal Investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Material Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221."

Please upload your template HIPAA Authorization language.

Do you have any additional HIPAA Authorization language?

No
LOCAL CONTEXT: Component Sites

As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites here, in the Institutional Profile, and for specific studies, as requested by the Reviewing IRB. If your component sites have information that differs from that provided in the previous section, specify the site and what differs below.

Do you have a component site on your FWA? No

Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.

These steps occur BEFORE the study is approved by the Reviewing IRB:

How should an investigator request to cede review to an external IRB? For example, should they email the IRB? Is there a specific person at the IRB? Should they just submit the request via your local IRB system (as outlined in the questions below)?

Investigator should submit the request via MMC local IRB system (eProtocol).

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely? No

These steps occur AFTER the study is approved by the Reviewing IRB: Indicate below what documentation and events are submitted to your local IRB when relying on an external IRB.

After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site’s sIRB approved documents before your site is activated/enrollment can begin? Yes

Should your investigator submit any of the following to your HRPP when ceding review to another institution? If checked, you will be asked to detail what should be submitted.

- Study-wide amendments (protocol or consent form modifications)
- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events
- Adverse events
- Final report

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review? Investigators should submit protocol, local and consent form amendments

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP? Amendments include personnel modifications, change of PI, study compensation, change in enrollment,
and what should be submitted when ceding review?  
approval letter from lead IRB and revised documents should be submitted to MMC local IRB

What should be submitted at continuing review?  
CR includes personnel modifications, change of PI, study compensation, change of enrollment, approval letter from lead IRB and revised documents should be submitted to MMC local IRB

What should be submitted for serious or continuing non-compliance?  
Serious or continuing non-compliance includes SAE forms and related reports

What should be submitted for unanticipated problems?  
Unanticipated problems includes SAE forms and related reports

What should be submitted for serious adverse events?  
Serious adverse events includes SAE forms and related reports

What should be submitted for adverse events?  
Adverse events includes AE forms and related reports

What should be submitted for final reports?  
Final reports includes closure forms and related reports

Who at your institution should be contacted if a Lead IRB wishes to report an unanticipated problem, a determination of serious or continuing non-compliance, or a suspension or termination?

Name  
Flora Ukoli, MD, MPH., IBCLC.

Email  
fukoli@mmc.edu

Phone Number  
(615) 327-5653

Section 4: The Study-Specific Reliance Plan  
The questions below have been harmonized with the SMART IRB Agreement Implementation Checklist and serve as your reliance preferences when serving as the IRB of record for other sites.

If you decide to serve as the Reviewing IRB in IREx, when you create the study, these preferences will appear as the basis for your SSRP. You may edit your responses for the study or for one (or more) sites, if requested, at your discretion.

Is your institution willing to serve as the IRB of Record for other institutions? If yes, more information on your reliance preferences/requirements will be collected below.  
No